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AGENTIA MEDICAMENTULUI SI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

		DM000226051	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm Straight	ВМК6F95	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
I.2. Declarația de conformitate CE	Declaratie de conformitate CE	8	9	BENCHMARK	?	\$	Ϋ	\$	\$	Ÿ	· · · · · · · · · · · · · · · · · · ·	
I.3. Certificatul CE	Certificat CE_Full Quality										Unita 🕑	
I.3. Certificatul CE	Certificat CE_Design Examination	Nr 🕥	Denumire 🔍	Den.comerc. 🧿	Model 🛇	Nr. catalog 🔍	Tara 🔍	Producatorul 🛇	Reprezentant 📿	Ordin 🛇	Data 🛇	Cod vamal
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DM000226051	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm Straight	ВМК6F95		PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192		
DM000226066	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm MP + 5F BER 120cm Select	BMK6F95MBER130	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226072	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 105cm MP + 5F BER 130cm Select	BMK6F105MBER130	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226060	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm Straight + 5F BER 130cm Select	BMK6F95BER130	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226078	CATETER INTRAVASCULAR MICROFLUX	Benchmark™	5F Select Catheter (120cm - H1)	PNS5F120H1	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226059	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm Straight + 5F SIM 120cm Select	BMK6F95SIM120	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226054	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 105cm MP	BMK6F105M	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226062	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm Straight + 5F SIM 130cm Select	BMK6F95SIM130	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226065	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 95cm MP + 5F SIM 120cm Select	BMK6F95M5IM120	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	
DM000226071	CATETER-GHID VASCULAR	Benchmark™	6F Benchmark 105cm Straight + 5F SIM 130cm Select	BMK6F105M5IM130	SUA	PENUMBRA, INC.	F.C.P.C. DATACONTROL S.R.L.	Rg04-000192	02-08-2019	

Страница 4 из 6 (Всего элементов: 60) 🔇 1 2 3 4 5 6 📀

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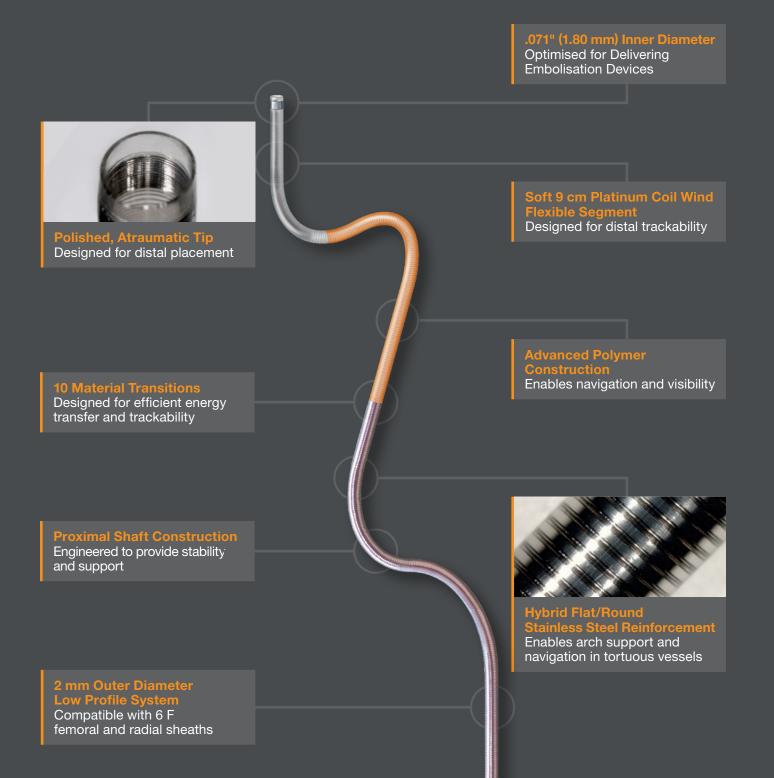
BENCHMARK 071

INTRACRANIAL ACCESS SYSTEM





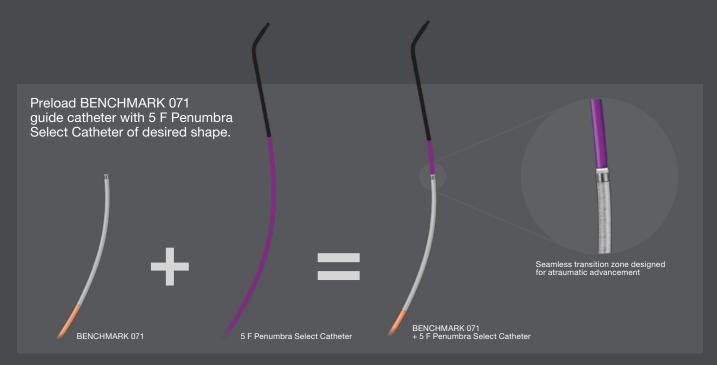
BENCHMARK 071 Key Design Features



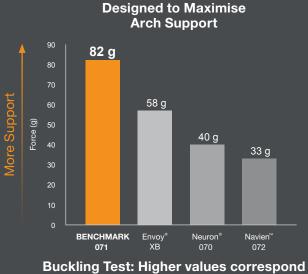
BENCHMARK 071 packaged with 5 F Penumbra Select Catheter

Advantages of Rapid Primary Access

- Faster procedures no need for an exchange
- Allows easy selection off of arch into desired vessel
- Facilitates atraumatic placement into distal vasculature
- Can be used for diagnostic angiogram .040" (1.02 mm) lumen
- Compatible with .035"-.038" (.89 mm-.97 mm) guidewires

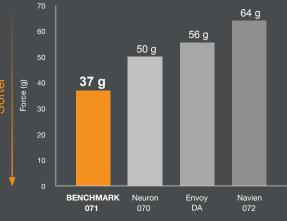


Performance Testing





Advanced Level of Tip Softness



Deflection Test: Lower values correspond to softer distal tip^b

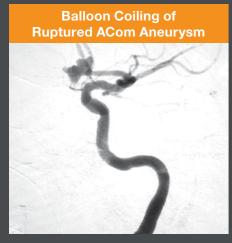
Femoral Access, Defined

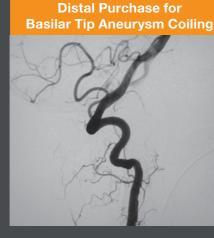
Designed for stability and compatibility with atraumatic navigation

Standalone or compatible with 6 F long sheath



BENCHMARK 071 Intracranial Access via Femoral Approach

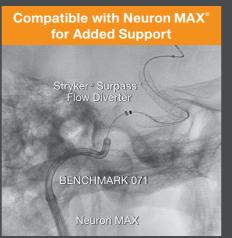






nts on file at Penumbra, Inc. Case examples presented are for informational purposes only. Results may not be predictive for all patients and may vary based on patie

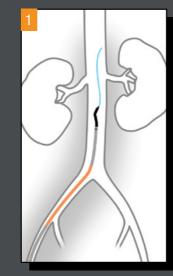
Images courtesy Drs. Yasha Kayan and Josser Delgado Abbott Northwestern Hospital, Minnesota, USA

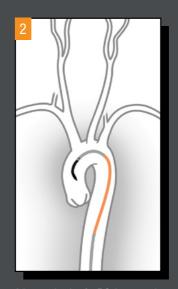


Stability Without Long Sheath



Rapid Primary Access — Typical Approach via Femoral Artery





Introduce the preloaded system over a guidewire and advance to a straight section of the abdominal aorta

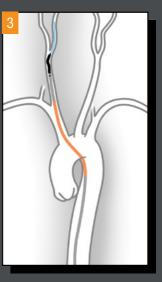
Advance the tip of 5 F Select over the guidewire into the ascending aorta while maintaining the position of BENCHMARK 071



With sufficient wire purchase, torque 5 F Select towards the first major turn



While maintaining position of 5 F Select and guidewire, advance BENCHMARK 071 into desired position



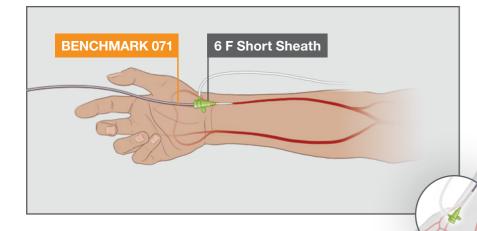
Advance 5 F Select and BENCHMARK 071 over the guidewire into the internal carotid artery



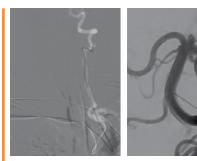
Remove 5 F Select while holding BENCHMARK 071 in position

Radial Advantage

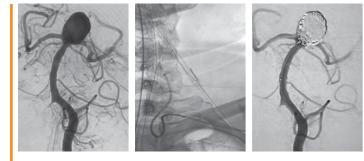
Low profile 2 mm OD compatible with the typical radial artery



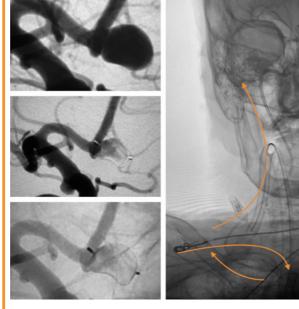
Hybrid stainless steel reinforcement engineered to provide kink resistance in aortic arch



Stent-Assisted Coiling Dr. Levansri Makalanda The Royal London Hospital London, UK



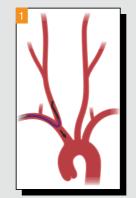
Primary Coiling Dr. Jean Delbrune Northside Hospital Florida, USA

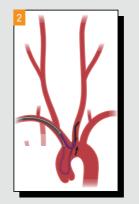


MicroVention® WEB® Embolisation Dr. Justin Singer Spectrum Health Michigan, USA

Images used with permission. Consents on file at Penumbra, Inc. Case examples presented are for informational purposes only. Results may not be predictive for all patients and may vary based on patient-specific attributes and other factors.

Rapid Primary Access — Typical Approach via Radial Artery





With BENCHMARK 071 and 5 F SIM Select in right subclavian artery, 5 F SIM Select is advanced forward into aortic arch

BENCHMARK 071 is moved forward over 5 F SIM Select in right subclavian artery, 5 F SIM Select is pulled back to access left CCA



5 F SIM Select is removed, while BENCHMARK 071 and .035" wire stay in CCA/ICA

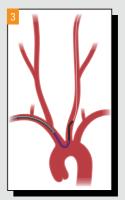
is advanced into ICA while wire stay in CCA/ICA

Data Presented at SNIS 2018

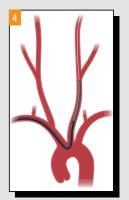
Radial Access for Cerebrovascular Intervention Using Penumbra BENCHMARK 071 Guiding Catheter[®]

36	Patients	Key
10	Primary Coiling	
8	Stent-Assisted Coiling	
5	Flow-Diverter Embolisation	
2	Balloon-Assisted Coiling	No
2	Wingspan [™] Stent-Assisted Coiling	
2	AVM or Dural AV Fistula	No
2	Vessel Sacrifice	site
1	Subclavian Stent	
1	Vasospasm Treatment	
3	Other	

c. Satti S, Rastogi S, Eden T, et al. E-031 Radial access for cerebrovascular intervention using penumbra benchmark 071 guiding catheter. J NeuroInterv Surg. 2018;10:A63-A64. doi: 10.1136/neurintsurg-2018-SNIS.107



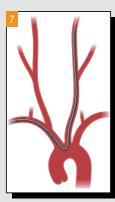
.035" wire is moved through 5 F SIM Select into left ICA



While 5 F SIM Select is left in place, BENCHMARK 071 is tracked into CCA



Switch to 5 F BER Select, which BENCHMARK 071 and .035"



BENCHMARK 071 is advanced over BER Select catheter into ICA, then 5 F Select is removed

Procedural and operative techniques and considerations are illustrative examples from physician experience. Physicians' treatment and technique decisions will vary based on their medical judgment.

Results

catheter-related complications

major radial access complications

BENCHMARK[®] 071 Kits

		BENCHN	IARK 071	5 F Select™ Catheter			
Catalog Number	Description	Length (cm)	Shape	Length (cm)	Shape		
BMK6F95BER120	BENCHMARK 071 KIT	95	Straight	120	BER		
BMK6F95MBER120	BENCHMARK 071 KIT	95	MP	120	BER		
BMK6F105BER130	BENCHMARK 071 KIT	105	Straight	130	BER		
BMK6F105MBER130	BENCHMARK 071 KIT	105	MP	130	BER		

BENCHMARK 071

BENCHMARK 071						
Catalog Number	Description	Length (cm)	Shape			
BMK6F95	BENCHMARK 071	95	Straight			
BMK6F95M	BENCHMARK 071	95	MP			
BMK6F105	BENCHMARK 071	105	Straight			
BMK6F105M	BENCHMARK 071	105	MP			
BMK6F115	BENCHMARK 071	115	Straight			
BMK6F115M	BENCHMARK 071	115	MP			

Tip Shapes

BENCHMARK 071	Select Catheter
Straight MP	H1 BER SIM

5 F Select Catheters

Catalog Number	Description	Working Length (cm)	Inner Diameter (in / mm)	Wire Compatibility (in / mm)	Shape
PNS5F120BER	5F Select Catheter	120	.040 (1.02)	.035–.038 (.89–.97)	BER
PNS5F130BER	5F Select Catheter	130	.040 (1.02)	.035038 (.8997)	BER
PNS5F130SIM	5F Select Catheter	130	.040 (1.02)	.035038 (.8997)	SIM
PNS5F120H1	5F Select Catheter	120	.040 (1.02)	.035038 (.8997)	H1
PNS5F130H1	5F Select Catheter	130	.040 (1.02)	.035–.038 (.89–.97)	H1

Prior to use, please refer to the Instructions for Use for complete product indications, contraindications, warnings, precautions, potential adverse events, and detailed instructions for use.

BENCHMARK Intracranial Access System -

The BENCHMARK Intractantial Access System = The BENCHMARK Intractantial Access System is intended for the introduction of interventional devices Into the peripheral, coronary, and neuro vasculature. **Potential Adverse Events** Possible complications include, but are not limited to, the following: acute occlusion; air embolism;

death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

NEURON MAX System – Intended Use The NEURON MAX System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. Potential Adverse Events Possible complications include, but are not limited to, the following: acute occlusion; air embolism; death; distal embolization; emboli; false aneurysm formation; hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.

NEURON Intracranial Access System – Intended Use The NEURON Intracranial Access System is intended for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. Potential Adverse Events

Possible complications include, but are not limited to, the following: acute occlusion; air embolism;

death; distal embolization; emboli; false aneurysm formation, hematoma or hemorrhage at puncture site; infection; intracranial hemorrhage; ischemia; neurological deficits including stroke; vessel spasm, thrombosis, dissection, or perforation.



mbra, Inc. USA Penu One Penumbra Place Alameda, CA 94502 USA 1.888.272.4606 T 1.510.748.3200 F 1.510.748.3232 order@penumbrainc.com info@penumbrainc.com

Penumbra Europe GmbH Am Borsigturm 4413507 Berlin Germany T +49 30 2005 676-0 F +49 30 2005 676-10 de-order@penumbrainc.com info@penumbrainc.de

Penumbra Neuro

 Penumbra Neuro

 Australia Pty Ltd

 Suite 3, Level 5, 1 0xford Street

 Darlinghurst NSW 2010

 Australia

 T +61-1300 817 025

 F +61-1300 817 025
order.anz@penumbrainc.com

Penumbra Latin America Distribuidora de Equipamentos e Produtos Médicos Ltda Avenida Brigadeiro Luís Antônio 3421 cj 201 CEP 01401-001 São Paulo, Brazil T 5511.2883.5825 order.la@penumbrainc.com

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